

### **REMARKS/ARGUMENTS**

Claims 9, 11, 19 and 20 have been amended to recite a hydroxyapatite sintered compact into which no active group is introduced.

These amendments in Claims 9, 11, 19 and 20 are supported by the following description on page 7, lines 12-18 of the specification:

“Therefore, the structure is immune to the problem of residue of active group on the surface of the calcium phosphate in contrast to the conventional method in which an active group is introduced in calcium phosphate. Thus, in contrast to the convention structure, this structure is immune to a risk of degradation in bioactivity of the calcium phosphate due to the residue of the active group.”

In other words, as is apparent from the description that no active group is introduced unlike the conventional art, the use of a hydroxyapatite sintered compact into which no active group is introduced as a hydroxyapatite sintered compact constituting a medical material and a hydroxyapatite complex according to the present invention is suggested in the present description in the specification. Therefore, the above amendments do not involve any new matter.

In Example 1 of the present application, after polymerization of a silk fibroin fiber with a silane coupling agent in a polymerization glass tube, cutting the silk fibroin fiber into a disc shape is carried out. It is impossible to cut the silk fibroin fiber into a disc shape in the polymerization glass tube. Therefore, after the polymerization of the silk fibroin fiber with the silane coupling agent, the silk fibroin fiber is collected, and thereafter the disc-shape cutting is carried out. At this time, an unreacted portion of the silane coupling agent does not remain on the silk fibroin fiber. That is, the silk fibroin fiber is cut into a disc shape at a place away from the place where the silk fibroin fiber has been treated with the silane coupling agent. With this

arrangement, the unreacted portion of the silane coupling agent is not reacted with the hydroxyapatite sintered compact.

Thereafter, in Example 1, the hydroxyapatite sintered compact particles are reacted with the silk fibroin fiber. It is clear that the hydroxyapatite sintered compact particles are hydroxyapatite which is not treated with the silane coupling agent and into which no active group is introduced. This is because Example 1 of the present invention never describes that the hydroxyapatite sintered compact particles were treated with the silane coupling agent.

Therefore, we believe it understandable from the description of Example 1 that the amendment clarifying that a hydroxyapatite sintered compact constituting a medical material and a hydroxyapatite complex according to the present invention is a hydroxyapatite sintered compact into which no active group is introduced, is not the addition of any new matter.

The Examiner has made final the following rejections of claims 9, 11, 13-17, 19 and 20:

1. Claims 9, 11, 13-17, 19 and 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by JP '511 as evidenced by Sato;
2. Claims 9, 11 and 19-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Hino*; and
3. Claims 13-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Hino*.

For the reasons set forth hereinafter, it is requested that the Examiner reconsider and withdraw these final rejections.

Amended Claims 9, 11, 19 and 20 have the structure in which a hydroxyapatite sintered compact into which no active group is introduced and a polymer-based material containing an

alkoxysilyl group are bonded. This is not disclosed or suggested in JP 511 (JP 2001-172511) and *Hino* (US 5814681).

In JP 511 (JP 2001-172511) and *Hino* (US 5814681) calcium phosphate into which an active group is introduced is bonded to a polymer-based material. Therefore, the structure in which a hydroxyapatite sintered compact constituting a hydroxyapatite complex is a hydroxyapatite sintered compact into which no active group is introduced cannot be easily arrived at on the basis of JP 511 (JP 2001-172511) and *Hino* (US 5814681) by a person skilled in the art.

Further, the hydroxyapatite complexes recited in Claims 9 and 19 and the medical materials recited in Claims 11 and 20 can exert bioactivity of the hydroxyapatite sintered compact. This effect cannot be obtained from the teachings of JP 511 (JP 2001-172511) and *Hino* (US 5814681).

That is, in the case of a calcium phosphate-polymer complex disclosed in JP 511 (JP 2001-172511), calcium phosphate is treated with the silane coupling agent, and the whole calcium phosphate is therefore coated with the silane coupling agent.

*Hino* (US 5814681) discloses that an organic group is introduced on the surface of a hydroxyapatite powder by using an organic silane coupling agent, such as  $\gamma$ -methacryloxypropyl trimethoxysilane. Therefore, in the restorative composition for hard tissue of *Hino* (US 5814681), the whole hydroxyapatite powder is coated with an organic silane coupling agent.

With this structure, intact bioactivity of the calcium phosphate particle is lost.

On the contrary, the present application employs a hydroxyapatite sintered compact into which no active group is introduced. This avoids bioactivity of calcium phosphate from being impaired by coating of calcium phosphate with an active group, unlike the calcium phosphate-

polymer complex disclosed in JP 511 (JP 2001-172511), etc. That is, the hydroxyapatite complex and the medical material of the present invention create the effect that they can exert bioactivity of the hydroxyapatite sintered compact without being impaired.

This effect is also described on page 7, lines 12-18, of the specification as follows:

“Therefore, the structure is immune to the problem of residue of active group on the surface of the calcium phosphate in contrast to the conventional method in which an active group is introduced in calcium phosphate. Thus, in contrast to the convention structure, this structure is immune to a risk of degradation in bioactivity of the calcium phosphate due to the residue of the active group.”

The Examiner has asserted that this effect is an unsupported effect. However, it is clear that the hydroxyapatite sintered compact into which no active group is introduced (i.e., intact hydroxyapatite sintered compact that is not coated with an artificially modified active group) is superior in bioactivity to calcium phosphate coated with a silane coupling agent.

That is, in the case of the calcium phosphate complexes disclosed in JP 511 (JP 2001-172511) and others, it is clear that intact bioactivity of hydroxyapatite is impaired since the calcium phosphate is coated with the silane coupling agent. On the other hand, it is clear that through the use of the hydroxyapatite sintered compact of the present invention, i.e., hydroxyapatite sintered compact into which no active group is introduced, its bioactivity is exerted without being impaired by an active group since the hydroxyapatite sintered compact of the present invention is not coated with an introduced active group. Therefore, without any evidence such as experimental data, it is clear that the invention of Claims 9, 11, 19 and 20 creates the above effect.

As herein described, the invention of amended Claims 9, 11, 19 and 20 is not disclosed or suggested in JP 511 (JP 2001-172511) and *Hino* (US 5814681); includes structure that could not be easily arrived at by even a person skilled in the art; and creates the effect that cannot be obtained from JP 511 (JP 2001-172511) and *Hino* (US 5814681).

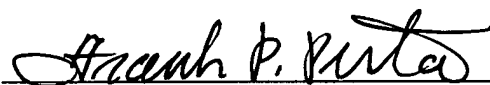
Therefore, the invention of Claims 9, 11, 19 and 20 is novel and nonobvious over JP 511 (JP 2001-172511) and *Hino* (US 5814681). Claims 13-17, which depend from Claim 20 are also novel and nonobvious over JP 511 (JP 2001-172511) and *Hino* (US 5814681).

The allowance of claims 1-8 and 18 is acknowledged.

In view of the above amendments and remarks, it is submitted that claims 9, 11, 13-17, 19 and 20 are allowable to Applicants, and formal allowance thereof is earnestly solicited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By:   
Frank P. Presta  
Reg. No. 19,828

FPP:cgp  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100